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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAN WADSTEIN and JAN REMMEREIT

Appeal 2009-009540
Application 09/410,484
Technology Center 1600

Decided: May 18, 2010

Before FRANCISCO C. PRATS, MELANIE L. McCOLLUM, and
STEPHEN WALSH, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a hypertension treatment method. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 1-3, 7, and 9 are on appeal (App. Br. 3). Claims 8 and 10-18 are also pending but have been withdrawn from consideration by the Examiner (*id.*). We will focus on claim 1, the only independent claim on appeal, which reads as follows:

1. A method of treating hypertension in humans comprising:
 - a) providing a hypertensive human patient in need of hypertension treatment and a composition comprising a safe and effective amount [of] conjugated linoleic acid for treating hypertension; and
 - b) administering said conjugated linoleic acid composition to said human patient so that blood pressure of said human patient is reduced.

Claims 1-3, 7, and 9 stand rejected under 35 U.S.C. § 103(a) as obvious over Cook¹ in view of Kawamura² and Shinitzky³ (Ans. 3).

The Examiner relies on Cook for disclosing “a method of reducing body fat comprising the administration of a safe and effective amount of conjugated linoleic acid” (Ans. 4).

The Examiner relies on Kawamura to “provide a nexus teaching between hypertension, weight loss and decreases in blood pressure” (*id.*). In particular, the Examiner finds that Kawamura “teach[es] that changes in body weight exhibited significant correlations with blood pressure reduction in hypertensive overweight human patients” (*id.*).

¹ Cook et al., US 5,554,646, Sep. 10, 1996.

² Minoru Kawamura et al., *Factors That Affect Calorie-Sensitive and Calorie-Insensitive Reduction in Blood Pressure During Short-term Calorie Restriction in Overweight Hypertensive Women*, 27 HYPERTENSION 408-413 (1996).

³ Shinitzky et al., US 4,474,773, Oct. 2, 1984.

The Examiner relies on Shinitzky for teaching “methods of treating warmblooded mammals comprising administering a pharmaceutically effective amount of a composition comprising 5-10% linoleic acid for the treatment of hypertension” (*id.*).

The Examiner concludes that it would have been obvious “to treat a hypertensive human patient with the conjugated linoleic acid method of Cook[]” (Ans. 5). In particular, the Examiner argues that “[o]ne of ordinary skill in the art would have been motivated to do this because Cook[] et al. provide a method of reducing body fat and Kawamura et al. teach that reduction in weight in hypertensive patients results in a lowering of blood pressure” (*id.*).

Appellants contend that, “as taught by Cook et al., linoleic acid does not reduce body weight” (App. Br. 9). More specifically, Appellants contend:

Cook *et al.* does not teach that administration of conjugated linoleic acid reduces bodyweight. In fact, Example 4 of Cook *et al.* explicitly teaches that when mice are fed a test diet containing conjugated linoleic acid or a control diet containing corn oil . . . , the mice fed conjugated linoleic acid have reduced body fat as compared to the controls, but the bodyweight is the same. Cook *et al.*, Column 3, lines 28-33. In Example 3, Cook *et al.* state that CLA administration reduces body fat in humans, but is silent as to whether bodyweight is decreased.

(Reply Br. 6.) Therefore, Appellants argue that “the Examiner’s attempt to link administration of conjugated linoleic acid to a decrease in bodyweight and thus reduced blood pressure is not supported by the references” (*id.* at 7). In addition, Appellants argue that Shinitzky does not cure this defect in the Examiner’s argument (*id.*).

ISSUE

Has the Examiner shown that Cook, Kawamura, and Shinitzky suggest administering conjugated linoleic acid to a hypertensive patient in need of hypertension treatment?

FINDINGS OF FACT

1. Cook discloses a “method of reducing body fat compris[ing] administering to the animal a safe and effective amount of a conjugated linoleic acid” (Cook, Abstract).

2. In particular, Cook discloses an example in which:

[M]ice were fed either a control (5.5% Corn Oil) or a CLA [i.e., conjugated linoleic acid] (5% Corn Oil and 0.5% CLA) containing diet for 28 days. . . . The results of the test show that although the overall weight of the control mice and the test mice was about the same, the total fat content of the test mice was significantly lower than that of the control mice.

(*Id.* at col. 3, ll. 1-32.)

3. Kawamura discloses: “Extensive studies have demonstrated an association between the overweight condition and hypertension. Prospective trials demonstrate that blood pressure is reduced by weight loss.”

(Kawamura 2⁴ (footnotes excluded).)

4. Kawamura also discloses that a “study was performed to elucidate the factors that affect the reduction in blood pressure produced by calorie restriction in overweight women with essential hypertension” (*id.* at 1).

⁴ The copy of this reference that is of record is paginated beginning at page one. In citing to this reference, we refer to the page numbers on this copy of the reference.

5. Kawamura states that the “reduction in blood pressure may be related in part to the amount of weight loss” (*id.* at 9).

6. Shinitzky discloses administering a pharmaceutically effective quantity of a fraction of lipids from natural sources for treating warm blooded mammals for dysfunctions of the immune system, increased vulnerability to bacterial contaminations, hypertension, and symptoms of withdrawal from morphine and alcohol, the lipid fraction including linoleic acid (Shinitzky, col. 12, ll. 22-30 & 41-46, & col. 13, ll. 42-51).

ANALYSIS

Kawamura discloses that there is “an association between the overweight condition and hypertension” and that “blood pressure is reduced by weight loss” (Finding of Fact (FF) 3; *see also* FF 5). Cook discloses a “method of reducing body fat compris[ing] administering to the animal a safe and effective amount of a conjugated linoleic acid” (FF 1). However, Cook does not disclose that administering conjugated linoleic acid results in weight loss (FF 2). Thus, we do not agree with the Examiner that Cook and Kawamura support the conclusion that administering conjugated linoleic acid would result in weight loss and thereby reduce blood pressure (Ans. 5). As a result, we do not agree that the Examiner has set forth a *prima facie* case that Cook and Kawamura suggest administering conjugated linoleic acid to a hypertensive patient in need of hypertension treatment.

Shinitzky discloses treating hypertension in warm blooded animals by administering a pharmaceutically effective quantity of a fraction of lipids from natural sources, the lipid fraction including linoleic acid (FF 6). However, the Examiner has not shown that Shinitzky’s composition

inherently contains conjugated linoleic acid. Also, while the Examiner has provided evidence that CLA is merely a set of positional isomers of linoleic acid, and that an ordinary artisan might therefore have considered CLA and linoleic acid to have similar properties (Ans. 5-6, 8-9, & 12), the linoleic acid in Shinitzky's composition is part of a complex mixture of lipid-based ingredients, and the Examiner has not adequately explained why an ordinary artisan would have undertaken the effort to substitute or include CLA in Shinitzky's complex composition, based solely on a potential similarity in properties. Thus, we agree with Appellants that the Examiner has not shown that Shinitzky overcomes the deficiencies of Cook and Kawamura.

CONCLUSION

The Examiner has not shown that Cook, Kawamura, and Shinitzky suggest administering conjugated linoleic acid to a hypertensive patient in need of hypertension treatment. We therefore reverse the obviousness rejection of claim 1 and of claims 2, 3, 7, and 9, which depend from claim 1.

REVERSED

alw

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